WEEK ENDING OCTOBER 31, 2014

OPP Weekly Activity Report

Highlights Include:

REGISTRATION DIVISION

Meeting Discussion On Amendment of Etofenprox All-Crop Wide-Area Mosquito Adulticide Tolerance On October 21, 2014, the Registration Division and the Health Effects Division met with Mitsui and their representatives from Landis International to discuss etofenprox residue data and an amendment to the existing wide-area mosquito adulticide tolerance. The centerpiece of this discussion was a presentation by Larry Holden from Sielken and Associates. Dr. Holden introduced a novel approach/concept derived from results of a large number of conventional etofenprox residue field trials in which the relative variation from the conventional residue trials and the magnitude from the mosquito adulticide trials are combined to provide better predicted residues resulting from future adulticide applications. This resulted in a proposal to lower the existing tolerance that will be considered by scientists in the Health Effects Division. (Kevin Sweeney, 703/305-5063)

USDA-Agricultural Research Service (ARS) Meeting on a New Class of Insect Repellents On October 27, 2014, USDA-ARS, Inter-Regional Research Project No. 4 (IR-4), and scientists met with members of OPP (Registration Division, Biopesticides & Pollution Prevention Division, and Kelly Sherman of the Office Director's office) to introduce the insect repellent uses of newly-discovered chromene analogs, which appear more potent than DEET. The presentation was based upon the patent: *"Preparation of compositions containing chromene derivatives and methods for repelling blood-sucking and biting insects, ticks, and mites" by Drs. Meepagal and Bernier*. The meeting served as a pre-registration discussion for chromene-based insect repellents for use on skin and fabric. USDA-ARS characterized the chemistry and spectrum of repellent activity while EPA informed them on the registration process, data requirements, and human studies. Chromenes appear to have great promise as repellents but an industry partner will be essential to their development due to the costs associated with the data requirements, manufacture, and marketing. (Kevin Sweeney, 703/305-5063)

New Auto-Dissemination Technology for Mosquito Control Meeting On October 27, 2014, SpringStar, Inc., Rutgers University, and Inter-Regional Research Project No. 4 (IR-4) met with members of the Registration Division and the Environmental Fate & Effects Division to discuss an improved approach to auto-dissemination of insect growth regulators by mosquitoes. Auto-dissemination is a process that enables female mosquitoes to move an insect growth regulator (IGR) from one container breeding site to the next when depositing eggs. Larvae that hatch from eggs in IGR-contaminated sites will die before becoming adults. The technology presented at this meeting was the result of a previous Experimental Use Permit (EUP) and research that showed how female mosquitoes seeking an egg-laying site can be passively contaminated with an IGR, which they will

spread from breeding site to another. This method is effective in the control of container-breeding mosquitoes in urban settings where traditional mosquito control practices are less effective. This method targets control of the principal vectors of West Nile, Chikungunya, and dengue viruses. More extensive greenhouse and field studies in the U.S. are expected in the coming year. (Kevin Sweeney, 703/305-5063)

Insect Repellent Study Design Discussion with S. C. Johnson On October 27 & 31, 2014, Kevin Sweeney of the Invertebrate-Vertebrate Branch 1 (IVB1) conducted two conference with S.C. Johnson scientists and regulatory staff to discuss some aspects of insect repellent field study design as a follow-up to a recent meeting with the OPP Director. SCJ scientist were seeking clarification on treatments and impacts of study design on repellency outcomes. (Kevin Sweeney, 703/305-5063)

Bill and Melinda Gates Foundation's Innovation to Impact Meeting On October 28, 2014, members of OPP's Registration Division attended a meeting hosted by the Gates Foundation held at the CropLife America offices in Washington, DC. The meeting was held to discuss potential EPA participation in an initiative by Gates Foundation to improve the availability of pesticide tools to combat mosquitoes, particularly in malaria-endemic countries. Many specifics were discussed, with a focus on EPA's processes and data requirements. Their "Innovation to Impact" effort proposes a collaborative approach with WHO, EPA, industry, and user and procurement authorities with a goal to investigate and reduce/remove barriers to the registration of new active ingredients or adding mosquito uses to currently-registered compounds. The attendees from OPP indicated an openness to participating in the program and will be in contact with the Foundation after having more in-depth internal discussions on how OPP would like to proceed. (Susan Jennings, 706/355-8574; Jeff Herndon, 703/305-6362; Marietta Echeverria, 305-8578; Kevin Sweeney, 305-5063)

Registration Division Registers New All-Crop Wide-Area Mosquito Adulticide Use On October 29, 2014, the Invertebrate-Vertebrate Branch 2 (IVB2) amended two mosquito adulticide products (EPA Registrations 1021-1795 and 1021-2562) to add an all-crop, wide-area mosquito adulticide use. This use pattern allows mosquito control districts to spray these products over crops for control of adult mosquitoes, which improves the efficiency and effectiveness of mosquito control programs. Concurrently, a ***Federal Register Notice*** was published to amend the prallethrin tolerance as described in 40 CFR Part 180.545 to add this use pattern. (Kevin Sweeney, 703/305-5063; Carmen Rodia, 306-0327; Richard Gebken, 305-6701)

Registration Actions Completed Under the Pesticide Registration Improvement Act (PRIA)					
Chemical	**Company**	**Registration Number**	**Action Code***	**Due Date**	**Response Date**
The Fungicide Branch granted:					
Tetraconazole	Arysta LifeScience North America, LLC	66330-422	R314	11/12/2014	10/28/2014
Heather Garvie, 703/308-0034					
Ethephon	NuFarm Americas, Inc.	228-727	R301	10/27/2014	10/23/2014
Marcel Howard, 703/305-6784					
The Herbicide Branch granted:					
Dicamba, dimethylamine salt	Agsaver, LLC	83772-11	R301	11/12/2014	10/28/2014
Erik Kraft, 703/308-9358					
			R301	12/4/2014	10/23/2014
Grant Rowland, 703/347-0254					
Flufenacet	Sharda USA LLC	83529-39	R310	11/3/2014	10/20/2014
Maggie Rudick, 703/347-0257					
The Insecticide Branch granted:					
Bifenthrin	Sergeant's Pet Products, Inc.	2517-171 2517-172	R300	11/3/2014	10/29/2014
Carlyn Petrella, 703/347-0439					
Tefluthrin	Syngenta Crop Protection, LLC	100-1545 100-1546	R310	11/4/2014	10/29/2014 10/30/2014
Linda DeLuise, 703/305-5428					
Phenothrin	McLaughlin Gormley King Company	1021-2562	R350	10/31/2014	10/29/2014
Piperonyl butoxide		1021-1795			
Kevin Sweeney, 703/305-5063					
The Insecticide-Rodenticide Branch granted:					
Imidacloprid	The Hartz Mountain Corporation	2596-183	R315	10/28/2014	10/27/2014
Autumn Metzger, 703/305-5314					

PRIA Categories

R300 – New product; identical or substantially similar in composition and use to a registered product; no data review or only product chemistry data; cite-all data citation or selective data citation where applicant owns all required data or submits specific authorization letter from data owner; category also includes 100% repackage of registered end-use or manufacturing-use product that requires no data submission or data matrix [(3)] [(4)]; **R301** – New product; or similar combination product (already registered) to an identical or substantially similar in composition and use to a registered product; registered source of active ingredient; selective data citation only for data on product chemistry and/or acute toxicity and/or public health pest efficacy, where applicant does not own all required data and does not have a specific authorization letter from data owner[(2)] [(3)]; **R310** – New end-use or manufacturing-use product with registered source(s) of active ingredient(s); includes products containing two or more registered active ingredients previously combined in other registered products; requires review of data package within RD only; includes data and/or waivers of data for only: product chemistry and/or acute toxicity and/or public health pest efficacy and/or child resistant packaging[(2)] [(3)]; **R314** – New end use product containing two or more registered active ingredients never before registered as this combination in a formulated product; new product label is identical or substantially similar to the labels of currently registered products which separately contain the respective component active ingredients; requires review of data package within RD only; includes data and/or waivers of data for only: product chemistry and/or; acute toxicity and/or; public health pest efficacy and/or; child resistant packaging[(2)] [(3)]; **R315** – New end-use non-food animal product with submission of two or more target animal safety studies; includes data and/or waivers of data for only: product chemistry and/or; acute toxicity and/or; public health pest efficacy and/or animal safety studies; and/or child resistant packaging [(2)] [(3)]; **R350** – Amendment requiring data review in science divisions (e.g., changes to REI, or PPE, or PHI, or use rate, or number of applications; or add aerial application; or modify GW/SW advisory statement)[(2)] [(3)]; and **R351** – Amendment adding a new unregistered source of active ingredient[(2)] [(3)].

ANTIMICROBIALS DIVISION

AD Initiates Registration Notice QA/QC Pilot. On Tuesday October 28, 2014, AD regulatory staff initiated a pilot program to improve the accuracy and consistency of registration notices and associated EPA-approved labeling. AD is conducting the pilot following a similar effort by the Registration Division and involves a secondary review of proposed notices/labeling by a QA/QC team prior to issuance to ensure the appropriate notice (e.g., conditional vs. unconditional registration) and format are used. The pilot is expected to last for several weeks and then, after conducting training for staff, to be adopted in late 2014 as a part of AD's formal standard operating procedures. (Julie Chao, 308-8735; Elizabeth Watkins, 346-0241)

EPA meets with FDA to discuss information on silver ion toxicity at FDA's College Park CFSAN Campus: On October 24th, scientists from AD met with FDA office of Food Contact Notification and USDA's Food Safety Inspection Service to discuss a recent study conducted by the FDA on silver ion toxicity. Discussions included study results, communication strategy and steps forward. OPP looks forward to further collaboration with the FDA on cross agency issues related to silver products. (Jonathan Leshin/RASSB, 703-347-0142)

FIELD & EXTERNAL AFFAIRS DIVISION

OPP Hosts Chinese Delegation On October 29, 2014, OPP hosted a delegation from China's Shandong Province. The delegation was composed of the Deputy Head of the Inspection Center of Food Quality (Jinan) Ministry of Agriculture, P.R. China, and researchers from the Shandong Academy of Agricultural Sciences. The group was accompanied by staff from the FDA. The purpose of the visit was to share how the EPA, Office of Pesticide Programs functions, manages the risk assessment and risk management process and to discuss similarities and differences between our two countries' programs. Health Affects and Pesticide Re-evaluation Divisions assisted Field and External Affairs Division in the briefing sessions. For more information about this visit contact Ron Kendall at 305-5561.

FEAD Participates in CTAG Board Meeting On October 28-29, staff from FEAD's Certification and Worker Protection Branch (CWPB) participated in a meeting of the Certification and Training Assessment Group (CTAG) Board of Directors. CWPB staff briefed the CTAG Board on the status of EPA's proposed changes to the Certification of Pesticide Applicators and Worker Protection Standard rules, and discussed the potential role of CTAG in assisting with rule implementation when EPA reaches that stage. The Board also discussed many other topics including improvement of pesticide applicator recertification programs, issues with using new distance-learning technologies for recertification (i.e., webinars, online

programs, etc.), the role of applicator training in pollinator protection and forthcoming pollinator protection plans, efforts to develop sustainable state applicator training programs, exam and manual development issues, and future priorities for CTAG. CTAG (http://www.ctaginfo.org) is a key worker safety program stakeholder group whose mission is to assess the current status and future needs of state applicator certification and training programs and facilitate improvement in and provide direction for the future of the national pesticide applicator certification program. The CTAG Board is made up of pesticide state lead agency and state cooperative extension service applicator certification program coordinators; it also includes EPA Headquarters and Regional representatives. (Kevin Keaney, 703-305-5557; Michelle Arling; Richard Pont).

OPP Holds a Three-Day Video Conference "Dry Run" to Review the Draft FIFRA Project Officer Training Course Regional pesticide managers met with OPP and OECA managers and staff via video conference this week to review a draft three-day FIFRA Project Officer Training Course that is being developed in FEAD. The training course is made up of 11 sessions that include the FIFRA statutory framework and OPP and OECA priority setting, the roles of the EPA offices and the project officers, the different phases of managing cooperative agreements, and how to build and maintain effective relationships with grantees. Feedback from the three-day dry run will be incorporated into the final version of the three-day, in-person FIFRA Project Officer Training Course which will be held in Crystal City in March 2015. (Cindy Wire, 415-947-4242)

Removal of Inert Ingredients from the approved Inert Ingredient List OPP will grant a 90 day extension request for public comment on the FR notice published on Wednesday, October 22, 2014. EPA is considering removing from its list of chemical substances that have been approved for use as inert ingredients in pesticide products 72 chemical substances that are no longer being used as inert ingredients in a pesticide product. The extension, when published, would allow stakeholders to submit comment by February 21, 2015.
(Cameo Smoot, FEAD, 305-5454)

INFORMATION TECHNOLOGY & RESOURCES MANAGEMENT DIVISION

New Web Page on Registration Maintenance Fees Available - The ITRMD Web Team worked with the Information Services Branch of ITRMD to publish information on Annual Pesticide Registration Maintenance Fees. All section 3 and section 24(c) registrations are subject to an annual maintenance fee described in FIFRA Section 4(i)(5). The fee per product will vary from year to year as the fee is dependent upon the projected number of products for which registrants will pay this fee. The fee for 2015 is $3,375. (Miriam Organic, 703-605-0583)

Guidance on Ebola Disinfectants Published - The ITRMD worked with AD and FEAD on guidance for disinfectants which can be used against the Ebola Virus. EPA has worked closely with Center for Disease Control (CDC) to develop infection controls in hospitals against the Ebola Virus.
Guidance to Companies on Referring to Registered Disinfectant Products that Meet the CDC Criteria for Use Against the Ebola Virus . (Miriam Organic, 605-0583)

Pesticide Advisory Committees Resource Directory Published - The ITRMD Web Team worked with FEAD to publish the Pesticide Advisory Committees and Regulatory Partners web area in the Drupal Web CMS, and established redirects from the old Pesticides website to the content in this new resource directory. Please visit the Pesticide Advisory Committees and Regulatory Partners resource directory home page at http://www2.epa.gov/pesticide-advisory-committees-and-regulatory-partners for more information. (ITRMD Web Team, 703-605-0564)

Updated DER Templates Published - The ITRMD Web Team worked with EFED to replace the study profile templates for Environmental Fate with updated versions on the Website. All of the 835 series templates were replaced. For the 850 series, the guidelines for 850.1710 & 850.1730 and 850.6100 were updated. For more information on this update, please visit the Study Profile Templates web page. (Christine Tran, 703-305-1577)

Minor Uses Website Updated - The ITRMD Web Team worked with RD to publish the documents relating to petitions requesting to extend the exclusive use period for the active ingredients metconazole, tetraconazole, and for a specific commodity, difenoconazole. Additional information on exclusive use periods can be found on the Agency's Minor Uses and Grower Resources website. (Christine Tran, 703-305-1577, Miriam Organic, 703-605-0583)

Microsoft Outlook and FOIA - Earlier this year, the Office of Environmental Information (OEI) became aware that limitations had identified with the Microsoft (MS) Outlook email search function. These limitations may have affected the completeness of results when employees conducted self-directed searches of email messages within MS Outlook. In response to these limitations, OPP had to re-examine over 500 FOIA cases to determine if email searches were conducted and effected by the search limitations. It was determined that less than 5 of these requests would require researching via of OEI E-discovery process. (Earl Ingram, 703-305-5456)

OPP FOIA Request Status Report for Oct. 20- 24, 2014

Requests Received		Requests Closed			Requests Open		
FY15	This Week	FY15	FYTD	This Week	FY15	Prior Years	Total
45	15	8	35	10	37	327	364

(Ana Espinoza, 703-347-0102)

BIOPESTICIDES & POLLUTION PREVENTION DIVISION

***Bacillus subtilis* strain IAB/BS03.** On October 17, BPPD posted a draft Biopesticides Registration Action Document and risk assessments in the public docket for a 15-day public comment period prior to registration of *Bacillus subtilis* strain IAB/BS03. The four new end-use pesticide products will be used to control bacterial or fungal pests in various grain, small fruit and vegetable crops, tree fruit and nut crops, grass seed crops, row crops such as sugarbeet, tobacco, sugarcane, hops, oil crops, greenhouse/shadehouse and landscape ornamental tree and plant crops. Additional uses include applications to garden and ornamental landscapes in home-owner and residential areas. Docket Number EPA-HQ-OPP-2013-0575. (Susanne Cerrelli, 703-308-8077)

BPPD /ABSTC call to discuss new EPA framework for corn rootworm resistance management. On October 23, the Biopesticide and Pollution Prevention Division held a conference call with the Agricultural Biotechnology Stewardship Technical Committee (an industry consortium consisting of biotech registrants) to answer questions on EPA's proposed changes to the current corn rootworm insect resistance management and remediation plans. The Agency's new proposal follows the SAP's (December 2013) recommendations and aims to extend the lifetime of Bt PIPs by using IPM with IRM, identifying resistant populations more effectively, and responding faster to corn rootworm resistance cases. The industry was informed of the Agency's intent to open a public docket to receive comments from stakeholders, such as growers, extension entomologists, industry, and other entities. (Jeannette Martinez 305-1016, Alan Reynolds 605-0515).

ENVIRONMENTAL FATE & EFFECTS DIVISION

EFED/OPP Scientists Discuss Spray Drift Data with Crop Life America (CLA) and Canadian Researcher. Faruque Khan and Charles Peck from EFED met with CLA representatives and Dr. Tom Wolf, President of AgriMetrix Research & Training, Saskatoon, Canada to discuss various technical issues related to data submitted last year by the CLA for consideration in the OPP risk assessment process. Dr. Wolf

is the principle scientist in generating spray drift deposition data for Agriculture and Agri-Food Canada (AAFC). During the meeting, EFED scientists and CLA representatives discussed numerous issues related to the AAFC data as well as spray drift research and collaboration with international entities and current buffer assessment tools related to ground boom applications proposed by the EPA and PMRA. Following these discussions, Dr. Wolf presented results from a recent field study, and EFED scientists described EPA's implementation of drift reduction technology (DRT) and the development of recommended DRT language for pesticide product labels. (Faruque Khan, 703-305-6127 & Chuck Peck 347-8064).

Exposure Modeling Public Meeting. On October 28, OPP held its biannual Exposure Modeling Public Meeting (EMPM). The EMPM is a public meeting for presentation and discussion of current issues related to modeling pesticide fate, transport, and exposure for risk assessment in regulatory context. For this and future meetings, the scope of EMPM has been expanded to include environmental modeling generally. During the October 28 meeting, EPA staff and external stakeholders presented approaches to terrestrial exposure modeling, population modeling in risk assessment, methods to estimate maximum aquatic exposures using monitoring data, modeling pesticide concentrations in urban runoff, and EFED guidance on considering unextracted residues in laboratory studies. The agenda, presentations, and attendees will be posted to the Federal Register Notice at www.regulations.gov, docket number EPA-HQ-OPP-2009-0879-0064. (Melanie Biscoe, 703-305-7106)

North American NAPPC Meeting. On October 22-23, OPP staff attended and participated in the 14th Annual North American Pollinator Protection Campaign (NAPPC) International Conference hosted by the U.S. Department of Agriculture. The meeting included presentations by members of the senior administration at USDA, EPA, and the White House; commercial beekeepers, scientists studying pollinator health as well as private land managers also provided presentations. Participants were given time to discuss ideas and share success stories on efforts to advance pollinator protection. OPP staff participated in a breakout session on pesticide education, which focused on distribution of an educational video and workbook for pesticide safety educators that was developed by NAPPC. (Mary Clock-Rust, 703-308-2718)

Pacific Northwest Pesticide Inspector Training. Charles Peck and Faruque Khan of the Environmental Fate and Effects Division (EFED) presented a training session on spray drift modeling to participants of the Pacific Northwest Pesticide Inspector Conference for State, Tribal, and Federal regulatory agencies, hosted by EPA Region X. The OPP presentation was focused on the spray drift assessment process and the demonstration of available tools for both screening-level and refined assessments. Other topics included national bee guidance, mosquito control issues, pesticide establishment inspections, and other enforcement/inspector

issues. The information presented should benefit both new and experienced investigators during their investigations of spray drift incidents. (Faruque Khan, 703-305-6127 and Chuck Peck, 703-347-8064)

EFED Employee Featured in NOWCC Newsletter. Jean Bethea, an administrative assistant for EFED's immediate office, was featured in NOWCC's October newsletter as providing outstanding support for EFED. The article described how Jean works tirelessly to manage the calendars and schedules of EFED's Division Director and Associate Directors, schedules interviews, updates EFED's tracking system, and cheerfully greets and escorts visitors to the office. The article also mentioned how Jean volunteered to coordinate "Feds Feeds Families Campaign' for EFED and organized an EFED Coffee Shop fundraiser, resulting in over 675 pounds of donated food contributions. For her quality performance, EFED's Division Director, Don Brady, recognized Jean with a Customer Service Award and a Quality of Worklife Award. (Don Brady, 703-305-7695).

HEALTH EFFECTS DIVISION

Dicrotophos Team Meets with Registrant Regarding Issues in the Preliminary Risk Assessment: The risk assessment team for dicrotophos met with AMVAC to discuss the Registration Review risk assessment. The risk assessment identified food and water dietary exposure exceedances using the Calendex steady state analysis. AMVAC proposed mitigation where the retreatment interval was increased to 21 days. EFED will be revising their drinking water assessment based on the proposed change. In addition, AMVAC had questions regarding the Re-Entry Interval (REI) and the volatilization screen. HED offered guidance on both of these questions. AMVAC plans to submit a request to lower the REI. (Thurston Morton, 305-6691; Elissa Reaves, 305-0312, Matt Lloyd, 308-0130; Ally Lamay, 605-0658; Shalu Shelat, 347-8660; Anna Lowit, 308-4135)

Ethylene Oxide (ETO) Team Meets with Registrant on GDCI Issued for Registration Review: The RAB4 risk assessment team for ethylene oxide (ETO) met with Balchem/ARC Specialty Products to discuss the need for additional exposure and toxicity studies required for Registration Review. ETO is a fumigant/sterilant registered for use to reduce microbials principally for whole/ground spices and medical/lab items. The registrant plans to submit exposure and modeling data to the agency in order to demonstrate de minimus exposure to worker and bystander from the fumigation use pattern of ETO, and to provide weight of evidence against the need for further toxicity and exposure studies. (Hanna Pope-Varsalona, 347-0106; Thurston Morton, 305-6691; Sue Hummel, 305-7689; Jeff Dawson, 305-7329; Ivan Nieves, 305-6382; Elissa Reaves, 305-0312)

Joint ICCVAM-ECVAM meeting on acute toxicity testing: On October 30, representatives from ICCVAM, NIEHS-NICEATM, European Union Reference

Laboratory for alternatives to animal testing (EURL-ECVAM) met to discuss on-going projects related to alternative approaches for acute oral and acute dermal toxicity testing. Opportunities to collaborate and to facilitate international harmonization were discussed. (Anna Lowit, 308-4135)

US Comments Sent on Draft OECD Test Guideline: Melissa Panger, EFED, and Christine Olinger, US National Coordinator for the OECD Test Guideline Program, compiled US comments on a draft updated OECD test guideline for fish Acute Toxicity. Comments were received from FDA, ORD, and OPP during this first public comment period. (Christine Olinger 305-5406)